



SPONSOR: Rep. Bentz & Sen. Townsend
Reps. Lynn, Seigfried; Sens. Sokola, Sturgeon

HOUSE OF REPRESENTATIVES
150th GENERAL ASSEMBLY

HOUSE BILL NO. 91
AS AMENDED BY
HOUSE AMENDMENT NO. 1

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HOSPITALS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

Section 1. Amend Chapter 10, of Title 16, of the Delaware Code by making deletions as shown by strike through, insertions as shown by underline and redesignating as follows:

~~§ 1001 Definitions.~~

~~As used in this chapter:~~

(1) ~~"Acute health-care facility" means any facility which is established, maintained and operated for the purpose of providing immediate and emergent care to individuals suffering from a life-threatening medical condition.~~

(2) ~~"Government unit" means the United States, State, county, municipality or other political subdivision or any department, division, board or other agency of any of the foregoing.~~

(3) ~~"Hospital" means a place devoted primarily to the maintenance and operation of facilities for the diagnosis, treatment or care for not less than 24 hours in any week of 4 or more nonrelated individuals suffering from illness, disease, injury or deformity or a place devoted primarily to providing for not less than 24 hours in any week of obstetrical or other medical or nursing care for 2 or more nonrelated individuals but does not include sanatoriums, rest homes, nursing homes or boarding homes.~~

(4) ~~"Person" means person, firm, association or corporation.~~

~~§ 1002 Purpose.~~

~~The purpose of this chapter is to provide for the development, establishment and enforcement of standards for the construction, maintenance and operation of hospitals, which, in the light of advancing knowledge, will promote safe and adequate treatment of such individuals in hospitals.~~

~~§ 1003 License requirement.~~

~~No person or government unit, acting severally or jointly with any other person or government unit shall construct, establish, conduct or maintain a hospital in this State without a license being issued under this chapter.~~

~~§ 1004 Application for license.~~

~~An application for license shall be made to the Department upon forms provided by it and shall contain such information as the Department may reasonably require, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as are lawfully prescribed under this chapter.~~

~~§ 1005 Issuance and renewal of license.~~

~~(a) Upon receipt of an application for license and the application fee of \$250 for hospitals with 100 beds or fewer and \$375 for hospitals with more than 100 beds, the Department shall issue a license if the applicant and hospital facilities meet the requirements established under this chapter.~~

~~(b) A license, unless sooner suspended or revoked, shall be renewed annually upon filing by the licensee and payment of an annual licensure fee of \$150 for hospitals with 100 beds or fewer and \$250 for hospitals with more than 100 beds.~~

~~(c) A provisional or restricted license as authorized by the Department shall be issued when health requirements are not met, upon payment of a licensure fee of \$150 for hospitals with 100 beds or fewer and \$250 for hospitals with more than 100 beds. For each hospital which has been issued a provisional or restricted license there shall be resubmission of the application fee for reinspection prior to the issuance of an annual license.~~

~~§ 1006 Denial or revocation of license, hearings and appeal.~~

~~(a) The Department shall have the authority to deny, suspend, or revoke a license in any case where it finds that there has been a failure to comply with this chapter or the rules and regulations issued under this chapter or the Hospital Infections Disclosure Act [Chapter 10A of this title] or § 1731A of Title 24 or § 903 of this title.~~

~~(b) Before any license issued under this chapter is denied, suspended or revoked, notice shall be given in writing to the holder of the license setting forth the particular reasons for such action. Such denial, suspension or revocation shall become effective 30 days after the mailing by registered mail or personal service of the notice, unless the applicant or licensee within such 30-day period shall give written notice to the Department requesting a hearing, in which case the notice shall be deemed to be suspended. If a hearing has been requested, the applicant or licensee shall be given an opportunity for a prompt and fair hearing before the Department. At any time at or prior to the hearing, the Department may rescind the notice of denial, suspension or revocation upon being satisfied that the reasons for denial, suspension or revocation have been or will be removed. A copy of the decision of the Department setting forth the finding of facts and the particular reasons for the decision shall be sent by registered mail or served personally upon the applicant or licensee. The decision shall become final 30 days after it is so mailed or served unless the applicant or licensee within such 30-day period appeals the decision to the Superior Court in accordance with § 1014 of this title.~~

~~(c) The procedure governing hearings authorized by this section shall be in accordance with rules promulgated by said Department.~~

~~(d) A full and complete record shall be kept of all proceedings, and all testimony shall be reported but need not be transcribed unless the decision is appealed pursuant to § 1014 of this title. A copy or copies of the transcript may be obtained by an interested party on payment of the cost of preparing such copy or copies. Witnesses may be subpoenaed by either party and shall be allowed fees at a rate prescribed by the aforesaid rules.~~

~~§ 1007 Rules, regulations and enforcement.~~

~~(a) The Department shall adopt, amend or repeal regulations governing the establishment and operation of hospitals. These regulations shall establish reasonable standards of equipment, capacity, sanitation and any conditions which might influence the health care received by patients or promote the purposes of this chapter.~~

~~(b) The Department shall further adopt regulations to ensure that hospital staff have ready access to a locked hospital bathroom in the event of an emergency.~~

~~§ 1008 Effective date of regulations.~~

~~Any hospital which is in operation at the time of adoption of any applicable regulation or standard adopted under this chapter shall be given by the Department a reasonable time, not exceeding 5 years, within which to comply with such regulations and standards.~~

~~§ 1009 Inspections and investigations.~~

~~The Department shall make or cause to be made such inspections and investigations as it may deem necessary.~~

~~§§ 1010, 1011. Hospital Advisory Council — Membership; appointment; terms of office; compensation; responsibilities and duties.~~

~~§ 1012 Information confidential.~~

~~Information received by the Department through filed reports, through inspections or as otherwise authorized under this chapter shall not be made public in such manner as to identify individuals or hospitals, except in a hearing pursuant to § 1006 of this title or when otherwise required by law or federal regulation.~~

~~§ 1013 Annual report of Department.~~

~~The Department shall prepare and publish an annual report of its activities and operations under this chapter.~~

~~§ 1014 Appeal to Superior Court; procedure.~~

~~Any applicant or licensee who is dissatisfied with the decision of the Department as a result of the hearing provided in § 1006 of this title may, within 30 days after the mailing or service of the notice of decision as provided in said section, file a notice of appeal to the Superior Court in the office of the Prothonotary of the Superior Court of the county in~~

~~which the hospital is located or to be located, and serve a copy of said notice of appeal upon the Department. The Department shall promptly certify and file with the Court a copy of the record and decision, including the transcript of the hearings on which the decision is based. Proceedings thereafter shall be governed by the Rules of the Superior Court of the State.~~

~~§ 1015 Penalties.~~

~~Any person constructing, establishing, conducting, managing or operating any hospital without a license shall be fined not more than \$50 for the first offense and not more than \$500 for each subsequent offense and each day of a continuing violation after conviction shall be considered a separate offense.~~

~~§ 1016 Injunction.~~

~~Notwithstanding the existence or pursuit of any other remedy, the Department may, in the manner provided by law, maintain an action in the name of the State for injunction or other process against any person or governmental unit to restrain or prevent the establishment, conduct, management or operation of a hospital without a license.~~

~~§ 1017 Waiver.~~

~~Any person who has presented plans for a hospital and received approval of them by the Department prior to June 28, 1968, shall be eligible for licensing until the fifth anniversary of such effective date of this chapter.~~

~~§ 1018 Maintaining anatomical gifts data.~~

~~§ 1019 Designation of acute health care facilities as stroke centers.~~

~~(a) The Secretary of Health and Social Services shall designate as a comprehensive stroke center any acute health-care facility within Delaware, or an out-of-state acute health-care facility upon request, which has received Advanced Certification for Comprehensive Stroke Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.~~

~~(b) The Secretary of Health and Social Services shall designate as a primary stroke center any acute health-care facility within Delaware, or an out-of-state acute health-care facility upon request, which has received Advanced Certification for Primary Stroke Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.~~

~~(c) The Secretary of Health and Social Services shall designate as an acute stroke ready center any acute health-care facility within Delaware, or an out-of-state acute health-care facility upon request, which has received Advanced Certification for Acute Stroke Ready Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.~~

~~(d) The Secretary of Health and Social Services may establish other distinct categories of stroke center certification if additional categories are established by the Joint Commission or by an equivalent nationally recognized guidelines-based accrediting organization as determined by the Secretary, and may designate any acute health-care facility as such based on certification by the Joint Commission or other nationally recognized guidelines-based accrediting organization.~~

~~(e) The Secretary shall suspend or revoke a facility's designation as a comprehensive stroke center, primary stroke center, acute stroke ready center or other categorization if the Joint Commission or equivalent nationally recognized guidelines-based accrediting organization as determined by the Secretary suspends or revokes a facility's certification.~~

~~§ 1020 Hospital visitation policy.~~

~~(a) Each hospital shall include in its visitation policy a provision allowing each competent adult patient to receive visits from any individual from whom a patient desires to receive visits, subject to restrictions contained in the visitation policy related to a patient's medical condition, the number of visitors simultaneously permitted in a patient's room, and the hospital's visitation hours, as well as protective orders issued by a court.~~

~~(b) Each hospital shall honor each adult patient's desires set forth in the adult patient's power of attorney documents, advance health-care directives, and any similar documents, in accordance with and subject to provisions related to same that appear in this chapter, Chapter 25 of this title, and Chapter 49 of Title 12.~~

~~(c) The duties and rights conferred by this section are in addition to, and not in derogation of, duties and rights otherwise conferred by law, including §§ 2508 and 5161 of this title.~~

~~(d) Nothing in 77 Del. Laws, c. 49 shall preclude a hospital from restricting visitations due to attempts to interfere with patient care, the presentation of a threat to staff, patients or hospital personnel, or other actions disruptive to hospital operations.~~

~~(e) Except as provided in subsection (d) of this section above, nothing in this section shall be read to overrule any decision of the Delaware Department of Correction.~~

§ 1001. Hospital defined.

As used in this Chapter, "hospital" means a health care organization that has a governing body, an organized medical and professional staff, and inpatient facilities, and provides either medical diagnosis, treatment and care, nursing and related services for ill and injured patients, or rehabilitation services for the rehabilitation of ill, injured or disabled patients 24- hours-per-day, seven-days-per-week and primarily engaged in providing inpatient services.

Hospitals may be further classified as:

(a) General - providing diverse patient services, diagnostic and therapeutic, for a variety of medical conditions. A general hospital must provide onsite:

(1) Diagnostic x-ray services with facilities and staff for a variety of procedures;

(2) Clinical laboratory services with facilities and with anatomical pathology services regularly and conveniently available; and

(3) Operating room service with facilities and staff.

(4) Emergency Department with facilities and staff.

(b) Long Term Care - providing inpatient services for patients whose medically complex conditions require a long hospital stay with an average length of stay of greater than 25 days.

(c) Psychiatric - providing services for the diagnosis and treatment of patients with psychiatric-related illness.

(d) Rehabilitation - providing intensive inpatient rehabilitative services for one or more conditions requiring rehabilitation.

§ 1002 Regulations

(a) The Department shall develop, establish and enforce standards governing the construction, maintenance and operation of hospitals to protect and promote the public health and welfare.

(b) The Department shall further adopt regulations to ensure that hospital staff have ready access to a locked hospital bathroom in the event of an emergency.

§ 1003 License requirement.

(a) No person shall construct, establish, conduct or maintain a hospital in this State without a license being issued under this Chapter.

(b) A license is not transferable from person to person or entity to entity.

(c) Separate Licenses

(1) Separate licenses are required for hospitals maintained on separate premises, even though both hospitals may be operated under the same management.

(2) Separate licenses are not required for separate buildings on the same grounds or adjoining grounds, if the buildings are operated under one management.

(3) All off-site ambulatory care service facilities must be licensed as free-standing facilities if identified as such in § 122(3) of this Title.

§ 1004. Application for license.

An application for license shall be made to the Department upon forms provided by it and shall contain such information as the Department may reasonably require including affirmative evidence of ability to comply with such reasonable standards, rules and regulations as are lawfully prescribed under this Chapter.

§ 1005. Issuance and renewal of license.

(a) The Department shall grant an initial license for a period of up to one year to a new hospital that completes the application process, submits the nonrefundable application fee of \$1,000 plus \$2 per licensed inpatient bed and \$500 for each emergency department not located on the hospital's main campus, and demonstrates compliance with the requirements established under this Chapter.

(b) The Department shall renew annually a hospital's license, unless suspended or revoked, upon filing by the hospital, payment of an annual licensure fee of \$750 plus \$2 per licensed inpatient bed and \$500 for each emergency department not located on the hospital's main campus, and demonstration of its continued compliance with the requirements established under this Chapter.

(c) The Department may grant a provisional license to a hospital which is not in substantial compliance with the requirements established under this Chapter. A hospital which has been issued a provisional license shall resubmit the initial application fee for reinspection prior to the issuance of an annual license.

(d) The licensure fees collected by the Department pursuant to this section are hereby appropriated to, and shall be retained by, the Department to defray operating expenses associated with this chapter.

§ 1006. Denial or revocation of license, hearings and appeal.

(a) The Department shall have the authority to deny, suspend, or revoke a license in any case where it finds that there has been a failure to comply with this Chapter or the rules and regulations issued under this Chapter or the Health-Care Associated Infections Disclosure Act [Chapter 10A of this Title] §1731A of Title 24 or §903 of this title.

(b) Before a license issued under this Chapter is denied, suspended or revoked, notice shall be given in writing to the holder of the license setting forth the particular reasons for such action. Denial, suspension or revocation of a license shall become effective 30 days after the mailing by registered mail or personal service of the notice, unless the applicant or licensee within such 30 day period shall give written notice to the Department requesting a hearing, in which case the notice shall be deemed to be suspended. If a hearing has been requested, the applicant or licensee shall be given an opportunity for a prompt and fair hearing before the Department. At any time at or prior to the hearing, the Department may rescind the notice of denial, suspension or revocation, upon being satisfied that the reasons for such action have been or will be removed. A copy of the decision of the Department setting forth the finding of facts and the particular reasons for the decision shall be sent by registered mail or served personally upon the applicant or licensee. The decision shall become

final 30 days after it is so mailed or served unless the applicant or licensee within such 30 day period appeals the decision to the Superior Court. A copy of said notice of appeal must be provided simultaneously to the Department. The Department shall promptly certify and file with the Court a copy of the record and decision, including the transcript of the hearings on which the decision is based. Proceedings thereafter shall be governed by the Rules of the Superior Court of the State.

(c) The procedure governing hearings authorized by this section shall be in accordance with rules promulgated by the Department. A full and complete record shall be kept of all proceedings and all testimony.

§ 1007. Enforcement

(a) Any person constructing, managing or operating any hospital without a license shall be fined not more than \$5,000 for the first offense and not more than \$10,000 for each subsequent offense. Each day of a continuing violation shall be considered a separate offense.

(b) The Department may impose civil money penalties for the violation of provisions of this chapter or the regulations adopted pursuant to it.

(1) A licensee or other person is liable for a civil money penalty of not more than \$10,000 per violation for violations which the Department determines pose a serious threat to the health and safety of a patient. Each day a violation continues constitutes a separate violation

(2) In determining the amount of a civil money penalty imposed pursuant to paragraphs (a) or (b) of this section, the Department shall consider the following factors:

a. The seriousness of the violation, including the nature, circumstances, extent and gravity of the violation and the threat or potential threat to the health or safety of patients;

b. The history of violations committed by the person or the person's affiliate, employee, or controlling person;

c. The efforts made by the hospital to correct the violation;

d. Any misrepresentation made to the Department; and

e. Any other matter that affects the health, safety or welfare of a patient.

(c) The Department shall have the authority to collect any civil money penalty. Any civil money penalties collected by the Department under this section are hereby appropriated to the Department to carry out the purposes of this section.

(1) Payment of any civil penalty by a facility is not an allowable cost for reimbursement under the state Medicaid program or under other state-funded programs.

(2) In the event of non-payment of a civil money penalty the Department may add the amount of the civil penalty to the licensing fee for the hospital. If the licensee refuses to make the payment at the time of the application for renewal of its license its license may not be renewed.

(3) In the event of non-payment of a civil money penalty after all legal appeals have been exhausted, a civil action may be brought by the Secretary in Superior Court for collection of the civil money penalty, including interest, attorney fees and costs. In a civil action to collect the civil money penalty the validity, amount and appropriateness of the civil money penalty shall not be subject to review.

§ 1008. Injunction.

Notwithstanding the existence or pursuit of any other remedy, the Department may, in the manner provided by law, maintain an action in the name of the State for injunction or other process against any person to restrain or prevent the construction, maintenance or operation of a hospital without a license.

§ 1009. Construction.

(a) All construction whether new or renovation, must conform to the design and construction standards established by the Department.

(1) A renovation is:

a. The strengthening or upgrading of building elements, materials, equipment, or fixtures that does not result in a reconfiguration of the building spaces within; or

b. Any reconfiguration of a space that affects an exit, a corridor, or any component of a means of egress;

or

c. Work that changes the current designated purpose or occupancy classification of a building space.

(2) Cosmetic changes such as repainting or changing carpeting are not considered renovations.

(b) When a hospital plans to construct or renovate any buildings or spaces within a building, two (2) copies of properly prepared plans and specifications for the entire project shall be submitted to the Department.

(c) An approval, in writing, shall be obtained from the Department before construction or renovation work is begun.

(d) Hospitals wishing to construct or renovate must apply to the Department and submit the appropriate fee for approval. The fee structure for plan review shall be as follows:

New Construction

<u>Square Footage</u>	<u>Fee</u>
<u>10,000 or less</u>	<u>\$250</u>

<u>10,001-20,000</u>	<u>\$300</u>
<u>20,001-30,000</u>	<u>\$350</u>
<u>30,001-40,000</u>	<u>\$400</u>
<u>40,001-50,000</u>	<u>\$450</u>
<u>50,001-above</u>	<u>\$500</u>

Renovations

<u>Square Footage</u>	<u>Fee</u>
<u>5,000 or less</u>	<u>\$100</u>
<u>5,001-10,000</u>	<u>\$150</u>
<u>10,001-15,000</u>	<u>\$200</u>
<u>15,001-20,000</u>	<u>\$250</u>
<u>20,001-25,000</u>	<u>\$300</u>
<u>25,001-30,000</u>	<u>\$350</u>
<u>30,001-35,000</u>	<u>\$400</u>
<u>35,001-40,000</u>	<u>\$450</u>
<u>40,001-above</u>	<u>\$500</u>

(e) After the hospital has submitted all required documentation, the Department shall review the submission within a timeframe agreed upon by both parties.

(f) Hospitals failing to complete the plan review process and receive approval prior to construction or renovation shall be subject to a \$5,000 fine for each project.

(g) Any licensure fees or fines collected by the Department pursuant to this section are hereby appropriated to, and shall be retained by, the Department to defray operating expenses associated with this chapter.

§ 1010. Inspections and investigations.

(a) The Department shall make or cause to be made such inspections and investigations of a hospital as it may deem necessary.

(b) The Department shall accept the survey report of an approved accrediting organization, as defined by regulations, in lieu of an annual licensure inspection.

§ 1011. Compliance.

All hospitals must comply with applicable Federal, State, County and Local laws and regulations.

§ 1012. Reportable Events.

(a) Hospitals must report all major adverse incidents involving a patient to the Department within ten (10) calendar days.

(1) A major adverse incident is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient. The Department shall define "major adverse incident" and provide further clarification in regulation.

(2) Major adverse incidents must be investigated by the hospital.

(3) A summary of the hospital's investigative findings will be forwarded to the Department within a timeframe agreeable to both parties.

(b) Hospitals must notify the Department immediately of any event occurring within the hospital that jeopardizes the health or safety of patients or employees including:

(1) An unscheduled interruption for three or more hours of physical plant or clinical services impacting the health or safety of patients or employees.

(2) A fire, disaster or accident which results in evacuation of patients out of the hospital.

(3) An alleged or suspected crime which endangers the life or safety of patients or employees, which is also reportable to the police department, and which results in an immediate on-site investigation by the police.

(c) Information submitted as a major adverse incident is considered peer review information and not subject to public disclosure except as aggregate data.

§ 1013. Designation of hospitals as primary stroke centers.

(a) The Secretary of Health and Social Services shall designate as a comprehensive stroke center any acute care hospital within Delaware, or an out-of-state acute care hospital upon request, which has received Advanced Certification for Comprehensive Stroke Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.

(b) The Secretary of Health and Social Services shall designate as a primary stroke center any acute care hospital within Delaware, or an out-of-state acute care hospital upon request, which has received Advanced Certification for Primary Stroke Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.

(c) The Secretary of Health and Social Services shall designate as an acute stroke ready center any acute health-care facility within Delaware, or an out-of-state acute health-care facility upon request, which has received Advanced Certification for Acute Stroke Ready Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.

(d) The Secretary of Health and Social Services shall designate as a thrombectomy-capable stroke center any acute health-care facility within Delaware, or an out-of-state acute health-care facility upon request, which has received Advanced Certification for Thrombectomy-Capable Stroke Centers issued by the Joint Commission or an equivalent certification by another nationally recognized guidelines-based accrediting organization as determined by the Secretary.

(e) The Secretary of Health and Social Services may establish other distinct categories of stroke center certification if additional categories are established by the Joint Commission or by an equivalent nationally recognized guidelines-based accrediting organization as determined by the Secretary, and may designate any acute health-care facility as such based on certification by the Joint Commission or other nationally recognized guidelines-based accrediting organization.

(f) The Secretary of Health and Social Services shall suspend or revoke a facility's designation as a comprehensive stroke center, primary stroke center, acute stroke ready center or other categorization if the Joint Commission or equivalent nationally recognized guidelines-based accrediting organization as determined by the Secretary suspends or revokes a facility's certification.

§ 1014. Hospital visitation policy.

(a) Each hospital shall include in its visitation policy a provision allowing each competent adult patient to receive visits from any individual from whom a patient desires to receive visits, subject to restrictions contained in the visitation policy related to a patient's medical condition, the number of visitors simultaneously permitted in a patient's room, and the hospital's visitation hours, as well as protective orders issued by a court.

(b) The duties and rights conferred by this section are in addition to, and not in derogation of, duties and rights otherwise conferred by law, including §§ 2508 and 5161 of this title.

(c) Nothing in this Chapter shall preclude a hospital from restricting visitations due to:

- (1) attempts to interfere with patient care; or
- (2) the presentation of a threat to staff, patients or hospital personnel; or
- (3) actions disruptive to hospital operations; or
- (4) pandemic or infectious disease outbreak.

(d) Except as provided in subsection (c) of this section, nothing in this section shall be read to overrule any decision of the Delaware Department of Correction.

§ 1015. Confidentiality of proprietary information.

Information obtained by the Secretary under this chapter shall be available to the public as provided in Chapter 100 of Title 29, unless the Secretary certifies such information to be proprietary. The Secretary may make such certification

where any person shows to the satisfaction of the Secretary that the information, or parts thereof, if made public, would divulge methods, processes or activities entitled to protection as trade secrets or as confidential financial or commercial information. Nothing in this section shall be construed as limiting the disclosure of information by the Secretary to any officer, employee or authorized representative of the state or federal government to effectuate the purposes of this chapter. Furthermore, nothing in this section shall prevent the Secretary from including in the remedial decision record information concerning the cost of the remedy or the manner in which it is performed. Prior to disclosure of information certified by the Secretary to be proprietary to an authorized representative who is not an officer or employee of the state or federal government, the person providing the proprietary information may require the representative to sign an agreement prohibiting disclosure of such information to anyone not authorized by this chapter or the terms of the agreement. Such agreement shall not preclude disclosure by the representative to any state or federal government officer or employee concerned with effecting this chapter.